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Czech Republic

Biotechnology

Status of Biotech Regulations--Central Europe 2004

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Report Highlights:

This report provides an overview of the current regulatory environment for biotech products in Austria, Czech Republic, Slovakia, Hungary, Slovenia, Croatia, and Bosnia and Herzegovina. Attitude of the region towards biotechnology is halfhearted at best with all countries except Bosnia and Herzegovina having implemented strict laws and regulations on the registration and commercial release of biotech products. Croatia, in an attempt to establish a "GMO-free" country, has already established a traceability system. Consumers' continued concerns and fears on biotechnology ensure political and regulatory opposition in most central European countries. A listing of related reports is included.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Vienna [AU1]
[EZ]

Legislation

Country	Applicable Laws and Regulations
Austria	<ul style="list-style-type: none"> - Directive 2001/18/EC on the deliberate release of genetically modified organisms, will be amended - Regulation on Novel Foods and Novel Food Ingredients (258/97/EC, 1139/98/EC, 49/00/EC, 50/00/EC) - Directive on the contained use of genetically modified micro-organisms (90/219/EC) - Directive on the legal protection of biotechnological inventions (98/44/EC) - EU Directives on seeds and varieties - Regulation on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs (2092/91/EC) - Ratified the Cartagena Protocol on Biosafety - Biotechnology Act (Law Gazette No 510/1994, amended by 94/2002) - Ordinance on Deliberate Release of GMO's into the Environment (Law Gazette II, No 49/1997) - Ordinances on Labeling of products that contain GMO's (Law Gazette II No 59/1998) and on Labeling of Genetically Modified Seeds (Law Gazette II No 74/1999) - Ordinance on Contamination of Seeds by Genetically Modified Organisms (Law Gazette II No 478/2001) - Ordinance on safety regulations when working with GMO's in closed systems (Law Gazette No II 431/2002)
Czech Republic	<ul style="list-style-type: none"> - Act 153/2000 based on EU rules, regulating registration and use of biotech products - Feed Act 91/1996 - Plant Varieties Act 219/2003 - Phytosanitary Act 147/1996 - New Act on GMOs should replace Act 153/2000, will implement EU Directive 18/2001
Slovakia	<ul style="list-style-type: none"> - Act No. 151/2002 on Use of Genetic Technologies and Genetically Modified Organisms, based on EU directives 98/83/EEC and 18/2001/EEC - Decree No. 252/2002 implementing the previous Act
Hungary	<ul style="list-style-type: none"> - 1998: 27th Act on Gene Technology Activities - 1999: 1st Order of the Minister of Agriculture and Regional Development on the Application of the Act on Gene Technology Activities - 1999: 44th Order of the Minister of Agriculture on the Fees and Charges of the Approval Process of Gene Technology Activities - 2000: 16th Order of Ministers of Agriculture, Health and Economy on the modification of the Hungarian Food Codex (related to biotech products) - 2000: 20th Order of the Government of Hungary on the approval process of Gene Technology - 2002: 67th Act - Amendment of the 27/1998 Act on Gene Technology Activities - 2003: 82nd Order of the Minister of Agriculture and Regional Development on the Registration and Data handling related to Gene Technology Activities, and the Documents Required with

	<p>Applications for Permit for Gene Technology Activities</p> <ul style="list-style-type: none"> - 2003: 148th Order of the Government of Hungary on Penalties related to Gene Technology Activities.
Slovenia	<ul style="list-style-type: none"> - Act Regulating Handling With Genetically Modified Organisms (Official gazette RS 67/2002) - Act Regulating the Sanitary Suitability of Foodstuff, Products and Materials Coming into Contact with Foodstuffs (official gazette RS 52/2000; 42/2002) - Rules On The Labeling Of Foodstuffs Produced From Genetically Modified Soy And From Genetically Modified Maize (Official gazette RS 105/2002) - Regulation On Labeling Foodstuff And Ingredients Containing Genetically Modified Additives And Aroma, Or Are Produced From Genetically Modified Organisms (Official gazette RS 105/2002)
Croatia	<ul style="list-style-type: none"> - Law on Consumer Protection, government gazette, no. 96/03 - Food Act, government gazette, no. 117/03. - Law on Protection of Nature, passed by Parliament 03/09/03, not yet published in the government gazette
Bosnia and Herzegovina	<p>Agricultural biotechnology does not have significant application yet. Except some basic biotechnologies (fermentation techniques, artificial insemination, micropropagation, tissue culture etc).</p>

Market Placement

Country	Requirements
Austria	<p>To get a product approved, the applicant must specify:</p> <ul style="list-style-type: none"> - item and the biotech product it contains - changes that the biotech product causes - possible safety risks - and provide an inspection and emergency plan. <p>In addition, the applicant should refer to special conditions for the use of the product, estimate the number of imports from and production in other EU/EEA countries, suggest packaging of the product to prevent unintentional multiplying of the biotech product during storage and make a proposal for labeling of the product.</p>
Czech Republic	<p>Product must be approved, registered and properly labeled. Application for approval must contain:</p> <ul style="list-style-type: none"> - detailed information about the user (person or a company) - information on a scientific advisor - purpose and time period of use for biotech product - detailed risk assessment - detailed information on the biotech product, method of its insert into the crop, its detection, if it was approved in some country, amount of biotech product to be used, etc. - information about biotech product, use, method of biotech detection, packaging, labeling
Slovakia	<p>The product must be tested, approved and properly labeled.</p>
Hungary	<p>Legislation prepared only for seeds so far. Seeds must be tested and approved.</p>
Slovenia	<p>Applicant must provide a risk assessment study for a product before applying for permission. The application must contain:</p> <ul style="list-style-type: none"> - technical documentation including:

	<ul style="list-style-type: none"> i. commercial name ii. producer, importer or distributor iii. person responsible for sample control iv. intended use of the product v. geographical area in type of the environment where product is intended to be used vi. potential users of the product <ul style="list-style-type: none"> - risk assessment - terms of putting product on the market including specific terms of its use and handling - program of monitoring of product's influence on the environment - period of validity of the permission - labeling, showing the biotech product containment - packaging
Croatia	<p>Permit needed. Before applying for a permit, a risk assessment study is mandatory. Each application must contain:</p> <ul style="list-style-type: none"> - technical documentation - risk assessment study - conditions of placing the product on the market - monitoring plan - time-span proposal for the permit - labeling and packaging proposal - summary of technical documentation <p>Another permit must be obtained for each additional application of approved Biotech products.</p>
Bosnia and Herzegovina	No applicable requirements yet.

Deliberate Release

Country	Testing Required	Requirements
Austria	YES	<p>"Step-by-step" approach, small-scale tests, then large tests.</p> <p>The applicant must provide:</p> <ul style="list-style-type: none"> - information about the genetic and pathogen characteristics of the biotech product - preconditions of the release - interaction between the biotech product and the environment - surveillance measures - time frame and place of the test <p>Province and the municipality, where the release is planned, may also issue a statement in the procedure.</p>
Czech Republic	YES	Variety has to be field tested for three years and approved according to Act 153/2000 for placement on the market, before it is approved for commercial growing.
Slovakia	YES	Field tests and registration of the variety have to be done.
Hungary	YES	In case of biotech plant varieties, field tests are required every several years. A complete packet of information required by GOH regulators for variety approval is the seed variety testing procedure set by the ISTA.

Slovenia	NO	In-country field test now not required.
Croatia	N/A	Before applying for a permit, a risk assessment study by an authorized company is mandatory (though existing risk assessment studies from other sources may be used, with the source's written consent). The permit application must contain: - technical documentation with prescribed parts - risk assessment - contingency plan - other relevant data
Bosnia and Herzegovina	NO	Not available yet.

Traceability

Country	Traceability System Existent	Details
Austria	NOT YET	N/A
Czech Republic	NOT YET	There is no traceability system being implemented yet.
Slovakia	NOT YET	A traceability system for agricultural products is in preparation.
Hungary	NOT YET	A traceability system for the products of agricultural biotechnology is not mandated.
Slovenia	NOT YET	A traceability system for agricultural products is in preparation.
Croatia	YES	Food business operators must establish a record keeping system of their suppliers and customers. Food placed on the market must be identified by specific documentation or other information.
Bosnia and Herzegovina	NOT YET	No laws and regulations yet.

Threshold

Austria	0.1% threshold for adventitious GMO "contamination" in seeds. This ordinance is likely to be modified once the EU introduces new "contamination" legislation on Novel Seed with thresholds between 0.3 and 0.7%.
Czech Republic	1% - requirement for labeling. There is no documentation needed for agricultural products containing over 1 percent of biotech product.
Slovakia	1% of adventitious presence now. This will be changed shortly to the EU level of 0.9%.
Hungary	N/A
Slovenia	1% - requirement for labeling
Croatia	The threshold is still undetermined, but under the Law on Protection of Nature, in cases where coincidental and technologically unavoidable traces of permitted biotech product are found, the government can determine the threshold below which the products need not be labeled.

Bosnia and Herzegovina	No laws or regulations yet.
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Labeling

Country	Special Labeling Required	Details
Austria	YES	The label must contain: <ul style="list-style-type: none"> - marking of the product and its biotech product - name of the producer or importer - statement on specific characteristics of the product that were caused by the biotech product - description of use of the product - statement on safety measures that will be taken in case of unintentional spread or misuse of the product, - instructions on storage and handling of the product
Czech Republic	YES	Label must say: "contains genetically modified organism". Terms like "biotech-free", "non-biotech", "GMO-free", or "may contain" do not appear in the Czech legislation.
Slovakia	YES	The label must contain the text: "this product contains GMOs" or "this product is made from GMO's". The text must be printed in the same font size as the text explaining the composition of the food product. There is no regulation on the use of labels such as "biotech-free", "non-biotech", etc., but labels of this kind may be used.
Hungary	NOT YET	Biotech food labeling and traceability legislation is not yet available. Hungary will strictly follow the EU policy and legislation on traceability and labeling.
Slovenia	YES	Label must contain the text: "izdelano iz gensko spremenjenega ... (name of the biotech product)" = produced from genetically modified.... At present, there is no legislation preventing use of GMO-free labels.
Croatia	YES	Label should contain: <ul style="list-style-type: none"> - special information about any ways in which the novel food or its ingredients no longer corresponds to the existing food or food ingredient - information about the changed characteristics or features, including the method used to produce that indication or characteristic The food and food ingredients containing (or consisting of) biotech products must have a visible indication that it contains or consists of GMOs. The indication must clearly state: "genetically modified organisms" or contain the sentence "this product contains genetically modified organisms." Food and food ingredients originating from biotech products but not containing them must have a visible indication that they originate from GMOs.
Bosnia and Herzegovina	NOT YET	No laws and regulations yet

Note: For more details and contacts for responsible authorities in all the above listed countries see the following reports:

AU3014 Status of Biotech Regulations-Austria

BK3013 Status of Biotech Regulations-Bosnia Herzegovina

HR3019 Status of Biotech Regulations-Croatia

EZ3012 Status of Biotech Regulations-Czech Republic

HU3012 Status of Biotech Regulations-Hungary

LO3005 Status of Biotech Regulations-Slovakia

SI3003 Status of Biotech Regulations-Slovenia

Other related reports included:

EZ3015 Biotech from a Czech Perspective

EZ3018, Status of Bt Corn Registration in Czech Republic

HR3024, Croatian Consumer Perceptions of Biotech

BK3015, BiH Consumer Perceptions of Biotech

HU3015, Consumer Perceptions of Biotech

AU3016, Carinthian Biotech Bill